NOV 2 5 2013

K133357

Page 1 of 6

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
November 22, 2013

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Rafael Sanguinetti
Director, CharrauSoft SA
Avda. Brasil 2807, Ap. 403
Montevideo, Uruguay, 11300
Tel: +598.270.92850
Email: rafael@charrua.com

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Product Name:	CharruaPACS System™
Common Name:	Picture, archive and communications system
Classification Name:	System, Image Processing, Radiological
Product Code:	LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

CharruaPACS™ system is substantially equivalent to:

Device Classification Name	system, image processing, radiological
510(k) Number	K080334
Device Name	INSTARAD
Original Applicant	MEDSPHERE TECHNOLOGIES PVT LTD.
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	02/07/2008
Decision Date	02/21/2008
Decision	substantially equivalent (SE)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology
summary	summary
Type	Traditional
Reviewed by Third Party	Yes
Expedited Review	No
Combination Product	No
Device Classification Name	system, image processing, radiological

Device Description: 21 CFR 807 92(a)(4)

The CharruaPACS System™ consists of the CharruaPACS Workstation/Server and the DICOM Viewer (CWS). The device is a software system to be used to handle and view DICOM compliant studies, which are stored within the device or specified network locations. The System supports DICOM C-STORE SCP for most used SOP classes, with uncompressed Transfer Syntax and JPEG lossless, JPEG lossy and JPEG 2000 Transfer Syntaxes, C-FIND and C-MOVE SCP Study Root model and C-ECHO Verification as SCP.

It is composed of four applications:

- Admin: for the initial configuration.
- DICOM Server.
- WEB Server: WEB server running on port 80, it allows to change CharruaPACS configuration and to access images through a web browser
- HTTP Client: a visualization application that accesses the images in the PACS through the HTTP port.

The servers run as Windows Services. It also uses the Independent JPEG group library for JPEG compression/decompression and the OpenJPEG group library for JPEG 2000 compression/decompression. The advanced version uses PostgreSQL as database. WebServer is based on Indy Project TIdHTTPServer.

The CharruaPACS System™ is intended for professional use, as a viewing tool for imaging studies, and is a 'Continuous Use' device. This device is also compliant with HIPAA regulations regarding patient privacy (such as restricting access to particular studies, logging access to data). There is no direct patient interaction with the device, therefore, there is no possibility that the CharruaPACS System might lead to a fatal fault or injury to the patient. The CharruaPACS System is intended to work as a standalone service that provides common PACS functionality.

The System has four main uses:

- Hard copy media replacement: PACS replaces hard-copy based means of managing medical images, such as film archives.
- Remote access: It expands on the possibilities of conventional systems by providing capabilities of off-site viewing and reporting (distance education, tele-diagnosis). It enables practitioners in different physical locations to access the same information simultaneously for teleradiology.
- Electronic image integration platform: PACS provides the electronic platform for radiology images interfacing with other medical automation systems such as Hospital Information System (HIS), Electronic Medical Record (EMR), Practice Management Software, and Radiology Information System (RIS).
- Radiology Workflow Management: PACS is used by radiology personnel to manage the workflow of patient exams.

Indications for Use: 21 CFR 807 92(a)(5)

CharruaPACS System™ is a software based device that receives digital images and data from various sources (e.g. CT scanners, MR scanners, ultrasound systems, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways, etc.). Images and data can be captured, stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA cleared monitor.

Technological Characteristics: 21 CFR 807 92(a)(6)

CharruaPACS System™ is a software product that handles and manipulates digital medical images. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed. In general, a PACS (Picture Archiving and Communication System) is a medical imaging technology which provides storage of, and convenient access to, images from multiple modalities. Electronic images and reports are transmitted digitally via PACS; this eliminates the need to manually file, retrieve, or transport film jackets. The universal format for PACS image storage and transfer is DICOM 3.x (Digital Imaging and Communications in Medicine). Non-image data, such as scanned

documents, may be incorporated using consumer industry standard formats like PDF (Portable Document Format), once encapsulated in DICOM.The modified device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices. Both systems have been developed to replace traditional film handling in radiology. The 2 devices are substantially equivalent in the areas of design, architecture, general function, application, and intended use.

Any difference between the two devices does not affect safety or efficacy. The predicate device and the new device are compared below:

Feature/Functions		**CharruaPACS Device**	**InstaRad K080334 Predicate**	**If different, Impact on Safety and or Efficacy**
Indications for Use		Picture, Archiving, Communications System	Picture, Archiving, Communications System	No difference.
Hardware server (recommended)	Computer processor	Intel i5 processor	Pentium dual core Intel Xeon 2.0+ GHz processor	Yes, differences. The predicate was based upon the latest computer platform at the time of development. Pentium dual core Intel xeon 2.0+ GHz processor are older technology and have been basically replaced with a current technology with an Intel i5 processor. The current system configuration has been tested and validated and the results of testing verified that there is no impact on safety or efficacy and that no additional risks have been identified.
	Operating System	Windows 7 Professional	Windows 2003	Yes, difference. The predicate was based upon the available Microsoft operating system for that time. Windows 2003 (server OS) which is no longer available or supported by Microsoft. Windows 2003 OS been replaced by Microsoft Windows 7. The system has been tested and validated with Windows 7 and the results of testing verified that there is no impact on safety or efficacy and that no additional risks have been identified.
	Hard disk array	Capacity depends on the usage volume. Minimum 400GB	Capacity depends on the usage volume. Minimum 400GB	No difference
	Ram	Minimum 4 GB	Minimum 1GB	Yes, differences. Microsoft Windows 7 OS and the Intel i5 processor require a larger RAM for operating. The system has been tested and validated with Windows 7 and the results of testing verified that there is no impact on safety or efficacy and that no additional risks have been identified.
Workstation Client Hardware (recommended)	Processor	Intel i5 processor	Pentium 2.0+Ghz. Dual core	Yes, differences. The predicate was based upon the latest computer platform at the time of development. Pentium dual core Intel Xeon 2.0+ GHz processor are older technology and have been replaced with Intel i5 processor or equivalent. The current system configuration with the Intel i5 processor has been tested and validated and the results of testing verified that there is no impact on safety or efficacy and that no additional risks

Feature/Functions		CharruaPACS Device	InstaRad K080334 Predicate	If different, Impact on Safety and or Efficacy
				have been identified.
	Operating System	Windows 7	Windows XP	Yes, difference. The predicate was based upon the available Microsoft operating system for that time. Windows XP which is no longer available or supported by Microsoft and Windows XP OS been replaced by Microsoft Windows 7. The system has been tested and validated with Windows 7 and the results of testing verified that there is no impact on safety or efficacy and no additional risks have been identified.
	Display	Medical Grade Monitor is recommended. Resolution depends on the modality type.	Medical Grade Monitor is recommended. Resolution depends on the modality type.	No difference
	RAM	Minimum 4 GB RAM	Minimum 1GB RAM	Yes, differences. Microsoft Windows 7 OS requires larger RAM then the old technology of Windows XP (which is no longer sold or supported by Microsoft). The system has been tested and validated with Windows 7 and the results of testing verified that there is no impact on safety or efficacy and that no additional risks have been identified.
	Hard Disk	400 GB minimum	400 GB minimum	No difference
Server features	System Architecture	Web based	Web based	No difference
	Hardware	Vendor Neutral	Vendor Neutral	No difference
	Security	Log-on user ID & password	Log-on user ID & password	No difference
	Remote monitoring	Yes	Yes	No difference
	Database	PostgreSQL	mySQL	Yes, differences. PostgreSQL is an open source object-relational database system. It has more than 15 years of active development and a proven architecture that has earned it a strong reputation for reliability, data integrity, and correctness. It runs on all major operating systems, including Linux, UNIX (AIX, BSD, HP-UX, SGI IRIX, Mac OS X, Solaris, Tru64), and Windows. It is fully ACID compliant, has full support for foreign keys, joins, views, triggers, and stored procedures (in multiple languages). It includes most SQL:2008 data types, including INTEGER, NUMERIC, BOOLEAN, CHAR, VARCHAR, DATE, INTERVAL, and TIMESTAMP. It also supports storage of binary large objects, including pictures, sounds, or video. It has native programming interfaces for C/C++, Java, .Net, Perl, Python, Ruby, Tcl, ODBC, among others. Both of these database systems use the Structured Query Language (SQL), but only PostgreSQL conforms to the standard set by the International Standards Organization (ISO). PostgreSQL is ACID (Atomicity, Consistency, Isolation, Durability). The system has been tested and validated

510(k) Summary

Feature/Functions		CharruaPACS Device	InstaRad K080334 Predicate	If different, Impact on Safety and or Efficacy
				and the results of testing verified that there is no impact on safety or efficacy and that no additional risks have been identified.
	Storage	RAID	RAID	No difference
Viewer Features:	Image Viewing Layout	Std formats(up to 2*3)	Std formats(up to 4*4)	Yes, Differences. In CharruaPACS there is one less "standard" format than the predicate. This difference is a user preference and does not directly affect the image or intended use. The system has been tested and validated and the results of testing verified that there is no impact on safety or efficacy and that no additional risks have been identified.
	WW/WL	Yes	Yes	No difference
	Zoom in/Zoom out	yes	yes	No difference
	Hounsfield Measurement	Yes	Yes	No difference
	Linear and angle measurements	Yes	Yes	No difference
	Series Comparison	Yes	Yes	No difference
	Scout line display	Yes	Yes	No difference
	3D capabilities	No	No	No difference
	Stack mode	Yes	Yes	No difference
	Gray scale invert	Yes	Yes	No difference
	Filters	Yes	Yes	No difference
	Rotate	Yes	Yes	No difference
	Key Image selection	Yes	Yes	No difference
	DICOM Print	Yes	Yes	No difference
	Windows print	Yes	Yes	No difference
	Query/Retrieve	Yes	Yes	No difference
	Image compression	Lossless streaming	Lossless streaming	No difference
	Selection tools	Thumbnails	Thumbnails	No difference
Reporting module	Reporting Interface	Can be opened from the viewer or from study list	Can be opened from the viewer or from study list	No difference
	Report Template Support	User Defined templates	User Defined templates	No difference
	Digital Signature	Yes	Yes	No difference
	Report Formats	DICOM SR	MS Word	Yes, Differences. MS Word documents are proprietary and only readable by Microsoft Word or compatible applications. DICOM SR is a open standard document readable by any competent DICOM Viewer. DICOM SR is saved in the PACS together with the images.

Feature/Functions		CharruaPACS Device	InstaRad K080334 Predicate	If different, impact on Safety and or Efficacy
				Word documents require some kind of reference to keep them linked to the study images and is not automatically linked as are DICOM SR reports. The system has been tested and validated and the results of testing verified that there is no impact on safety or efficacy and that no additional risks have been identified.
Other features	Link to Hospital Information System (HIS)	Yes	Yes	No difference
	Link to Radiology Information System RIIS)	Yes	Yes	No difference
	Electronic patient record	Through Broker Software	Through Broker Software	No difference
	HIPAA	Compliant	Compliant	No difference

Nonclinical Testing:

The complete CharruaPACS System™ configuration has been assessed and tested at the factory and has passed all in-house testing criteria. The Verification & Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed by the CharruaPACS System™ software in each operational mode and followed the process documented in the Validation Test Plan.

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met. If the device is installed by ChurrauSoft SA, integration and installations verification tests are conducted against acceptance criteria prior to release to the client.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for CharruaPACS System™ contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The subject device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The subject and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The modification to the subject device does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

Therefore, CharruaPACS System™ is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 25, 2013

CharruaSoft SA
% Mr. Carl Alletto
Consultant
111 Melanie Drive
AUBREY TX 76227

Re: K133357
Trade/Device Name: CharruaPACS System™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 25, 2013
Received: November 1, 2013

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

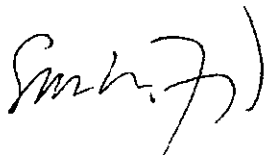
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133357

Device Name: CharruaPACS System™

Indications For Use:

CharruaPACS System™ is a software based device that receives digital images and data from various sources (e.g. CT scanners, MR scanners, ultrasound systems, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways, etc.).

Images and data can be captured, stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation.

Mammographic images may only be interpreted using an FDA cleared monitor.

Prescription Use _X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) ___K133357_____